11/1/03 DRAFT

RULES
OF
THE TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

CHAPTER 0720—2
DEFINITIONS

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0720—2—.01 DEFINITIONS. The following terms shall have the following meanings.

(1) ***"Adult psychiatric"*** means inpatient mental health services provided to patients over ~~21~~18 years of age.[1]

() *"Agency"* means the Tennessee Health Services and Development Agency.[2]

(2) ***"Ambulatory surgical treatment center"*** means any institution, place or building devoted primarily to the performance of surgical procedures on an outpatient basis.[3]

() *"Board"* means the State Health Planning and Advisory Board, created by T.C.A. Title 68, Chapter 11, Part 16, to develop the state health plan and other related studies.[4]

(3) ***"Capital expenditure"*** in relation to a proposed establishment of,[5]modification, renovation, or addition to a health care institution, means an expenditure by or on behalf of a health care institution which, under generally accepted accounting principals, is not properly chargeable as an expense of operation and maintenance. Any series of expenditures, each less than the threshold, but which when taken together are in excess of the threshold, directed toward the accomplishment of a single goal or project, requires a certificate of need. Any series of related expenditures made over a twelve (12) month period will be presumed to be a single project.

(a) *Establishment,* ***Modifications, additions, or renovations***. In calculating the capital expenditure for establishment, modifications, additions, or renovations "capital expenditure" is the amount per construction bid or total amount of invoices for the single project excluding major medical equipment.

(b) ***Equipment.*** The cost of major medical equipment over $1.5[6] million is not considered when determining the amount of capital expenditures for determining whether the ~~$2 million~~ monetary threshold of T.C.A. §68-11-1607[7] is met for an establishment, modification, addition, or renovation. The cost of all other equipment, whether fixed or moveable, is considered. The cost of major medical equipment is considered in calculating the amount of the examination fee. The cost for such fixed and moveable equipment includes, but is not necessarily limited to, taxes, government fees, assessments, and any other fees, assessments or charges directly associated with the acquisition of the equipment.

(c) ***Lease, loan, or gift***. In calculating the value of [8]the case of a lease, loan, or gift, the "cost" is the fair market value of the ~~equipment~~ above-described expenditures. In the case of a lease, the cost is the fair market value of the lease or the total amount of the lease payment, whichever is greater.[9]

(4) ***"Certification period"*** means the period of time beginning on the date of issuance of a certificate of need and ending on the expiration date of a certificate of need, as established by statute, rule, or order of the Agency.

(5) ***"Change of location"*** means a change of the specific location of an existing institution, facility, service, or piece of major medical equipment, in part or in its entirety. ~~The relocation of a parent office of a home health agency within the same county is not considered a change of location of a health care institution.~~[10] The following activities involving a home health agency are a change of location of a health care institution, and require a certificate of need:

(a) The addition of one or more counties to the licensed service-area of a home health agency;

(b) The change of location of a parent office to a different county~~;~~.

~~(c) The establishment of a "sub-unit" of a home health agency.~~[11]

(6) ***"Child and adolescent psychiatric"*** means inpatient mental health services provided to patients ~~up to and including 21~~individuals under 18 years of age.[12]

() *"Executive Director"* means the chief administrative officer of the Agency and the appointing authority, exercising general supervision over all persons employed by the Agency, as defined in *T.C.A. §68-11-1606.*[13]

(7) ***"Expiration date"*** is the date upon which a certificate of need expires and becomes null and void. The expiration date may be established by statute, by rule, or by order of the Agency.

() *"Fair market value"*[14]

(8) ***"Home health service"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

(9) ***"Hospital"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

~~(10) ***"Hospital projects"*** as used in *T.C.A. §68-11-1609* to determine the period of validity, is limited to hospital projects involving capital costs expenditures of $25 million or greater.~~

(11) ***"Long-term categories"*** includes nursing home services, regardless of the length of stay, and any other health service which is intended or reasonably expected to result in an average length of stay of 21 days or longer.

(12) ***"Major medical equipment" — "Cost."***

(a) As used in *T.C.A. §68-11-1602.* "major medical equipment" means any single item of equipment. or a series of components with related functions, within the definition and cost threshold set forth the referenced statute~~.~~, and which costs more than the amounts determined under *T.C.A. §68-11-1607.*[15]

(b) The cost of major medical equipment includes all costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following:

1. maintenance agreements, covering the expected useful life of the equipment;

2. federal, state, and local taxes and other government assessments; and

3. installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding.

(c) Any individual components or a piece of medical equipment with related functions, which are purchased over a 12 month period shall be considered toward the cost of the piece of major medical equipment.

(d) If the acquisition is by lease, the cost is either the fair market value of the equipment, or the total amount of the lease payments, whichever is greater

(13) ***"Mental health hospital"*** means ~~an inpatient facility which is held out to the public as a hospital, and in connection with the services of a physician, offers diagnosis, treatment, and care to mentally ill individuals on a comprehensive inpatient basis~~ a public or private hospital or facility or part of a hospital or facility equipped to provide inpatient care and treatment for persons with mental illness or serious emotional disturbance,[16] as licensed by the Department of Mental Health and Developmental Disabilities.

(14) ***"Mental health residential treatment facility"*** means a community-based or hospital affiliated facility or unit that offers 24-hour residential care, as well as, a treatment and rehabilitation component for ~~mentally ill~~ individuals with mental illness. The focus of the program may be on short-term crisis stabilization or on long-term rehabilitation that includes training in community living skills, vocational skills, and/or socialization. The staff includes direct-care staff as well as mental health treatment staff. The facility offers relatively high intensity treatment program(s), and requires a relatively high level of supervision for the residents/patients. ~~The population served by such facilities may be at a high risk of hospitalization or institutionalization because of the pervasive nature of their problems.~~[17]

(15) ***"Mental retardation institutional habilitation facility"*** means a facility which offers on a regular basis health related services to individuals with mental retardation who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but, because of physical or mental condition require residential care and services (more than room and board) and involves health related care under the supervision of a physician. Such a facility also offers an intensive program of habilitative services, as licensed by the Department of Mental Health and Developmental Disabilities.

(16) ***"~~Neonatal intensive care nursery~~Neonatal intensive care unit"***[18] means a special care unit staffed and equipped to provide professional intensive treatment for the care of seriously ill newborn infants and high-risk newborn infants, staffed by a neonatologist and specialized nurses and in which bassinets are used as licensed beds.

(17) ***"Not directly related to patient care"*** may include the following types of single, isolated expenditures:

(a) Telephone systems;

(b) Non-clinical data processing systems;

(c) Heating and/or air conditioning systems;

(d) Energy conservation devices;

(e) Parking facilities;

(f) Roof repairs;

(g) Medical office buildings;

(h) Warehouses; and

(i) Cafeterias.

(18) ***"Nursing home"*** is as defined in *T.C.A.* Title 68. Chapter 11, Part 2.

(19) ***"Outpatient diagnostic center"*** means a freestanding facility, program or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars ($10,000) or more exceeds five hundred thousand dollars ($500,000).~~any agency, institution, facility or place which primarily performs diagnostic procedures on an outpatient basis only.~~ [19] [20] [21] [22]

(20) ***"Person"*** where the context requires, may refer to any natural person, legal entity, facility, or institution, as defined in *T.C.A. §68-11-1602.*[23]

(21) ***"Recuperation center"*** is as defined in *T.C.A.* Title 68, Chapter 11, Part 2.

(22) ~~***"Rehabilitation"*** means an inpatient health care service provided with the purpose of assisting in the restoration or improvement of physical functions of physically disabled persons.~~[24]

(23) ***"Residential hospice"*** is as defined in *T.C.A.* Title 68. Chapter 11, Part 2.

(24) ***"Service area"*** means the county or counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide services and in which the majority of its service recipients reside.[25]

(25) ~~***"Sub-unit"*** means a semi-autonomous home health agency, which serves patients in a geographic area different from that of its parent home health agency. The sub-unit is located at such a distance from the parent home health agency, so as to require a separate license by the Department of Health.~~[26]

(26) ***"Substantive amendment"*** as used in *T.C.A. §68—11—1607* means any amendment which has the effect of increasing the number of beds, square footage, cost, or other elements which are reasonably considered in the discretion of the Agency [27] to be integral components of the application. A reduction of the above referenced components may be considered a substantive amendment if the amendment and supporting documentation are not received by the staff and Agency in a timely manner, necessary to allow the Agency to make an informed decision. Nothing in this rule shall be interpreted as limiting the Agency's authority to approve or deny all or part of any given application.

Authority: *T.C.A. §§ 68—11—1605; 4—5—202.*

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[1] Proposed by Ms. Janice Spillman of the Department of Mental Health and Developmental Disabilities. Mr. Noel Falls questioned whether the proposal would conflict with Medicaid reimbursement for individuals between the ages of 18 and 21. Ms. Spillman commented that her proposal would pose no such problems.

[2] Agency Staff proposed to define a term employed by the new statute.

[3] Mr. John Wellborn of Development Support Group submitted the following comment:

> Like "ODC", an "ASTC" may need a new definition to protect private medical practices from uncertainty about CON requirements. Surgeries of many types are appropriately performed in physician offices and are not a legislative concern. It might be helpful to redefine ASTC as "any institution, place, or building devoted primarily to the performance of surgical procedures of types defined by Medicare as reimbursable with a technical/facility fee, and/or requiring general anesthesia.
>
> This language would exclude such simple procedures as lasik refractive eye surgeries, but would include the riskier procedures done under general anesthesia and would include all types of procedures which are performed in hospitals. The word "primarily" is retained to give the Agency appropriate flexibility.

[4] Agency Staff proposed to define a term employed by the new statute.

[5] Agency Staff proposed that the *establishment* of the things listed in the definition be included, in addition to the modification, additions and renovations thereof, because there is no basis in the statute or practice for excluding such capital outlays from the definition.
[6] Agency Staff proposed that the rule be amended to reflect the dollar thresholds contained in the new statute.
[7] Id.
[8] Amendment proposed by Ms. Weaver.
[9] Agency Staff proposed the calculation of the value of a lease, since the general definition did not provide adequate guidance concerning leases.
[10] A change to the definition of "change of location" was proposed because legislation was signed into law on May 5, 2003 that addresses the relocation of the parent office of a home health agency or hospice within the same county. [Chapter No. 69, Senate Bill No. 461]
[11] Agency Staff proposes the amendment because "Sub unit" is no longer a term of any relevance.
[12] See footnote #1, above.
[13] Agency Staff proposed to define a term employed by the new statute.
[14] Jerry Taylor, Esq. of Farris Mathew Branan Bobango & Hellen made the following suggestion:

> Currently, there is no definition of "fair market value" regarding the lease of <u>space</u> (as opposed to equipment, as provided in subsection (12)(b)). In the absence of such a definition in the Rules, the policy has been to require an applicant to use the higher of the appraised value of the entire building, pro-rated to the amount of square feet being leased therein, or the total of the lease payments over the term of the lease. The pro-rated, appraised value of the space is usually significantly higher than the actual lease payments over the term of the lease. The latter, however, more closely represents the fair market value of the lease. The pro-rated, appraised value may be an accurate reflection of the value of fee simple ownership of the space in question, but is not accurately reflective of the value of a leasehold interest.
>
> I would suggest a specific definition for fair market value of office space, to be "the total amount of the lease payments for the leased space, over the entire term of the lease agreement, or for two years, whichever is greater."

[15] Agency Staff proposed that the rule reference the statute where the dollar threshold of "major medical equipment" is provided, so that further amendment need not be made if and when the amount in the statute changes.
[16] Ms. Janice Spillman of the Tennessee Department of Mental Health and Developmental Disabilities has suggested that the rule be amended to "use the definition of hospital in the mental health and developmental disability law, which is found at T.C.A. Section 33-1-101(13). . ." She also requested that the following be added to the end of the hospital definition "as defined in T.C.A. Section 33-1-101(13) and licensed by DMHDD." Agency Staff would note that the following is the definition, found at T.C.A. 33-1-101(13), to which Ms. Spellman refers: "<u>Hospital</u> means a public or private hospital or facility or part of a hospital or facility equipped to provide inpatient care and treatment for persons with mental illness or serious emotional disturbance."
[17] Changes to the definition were proposed by Ms. Janice Spillman of the Department of Mental Health and Developmental Disabilities.
[18] Dr. Shackleford proposed the amendment because "[i]n the Dept. of Health Regionalized Perinatal Program, the name used is *Neonatal Intensive Care Unit* or *NICU*, at least in the Rules. It is not included in 68-1-801."
[19] Agency Staff suggested that several other states have a minimum dollar amount threshold for the diagnostic equipment to be used. Some providers are performing *non-covered services*, such as sleep labs and computed tomography, that may technically fall under the current definition of ODC, but do not necessarily affect health costs and planning generally to a degree sufficient to justify CON review. Borrowing heavily from the statutory definition in North Carolina, which requires a CON for the establishment of a "diagnostic center," Agency Staff proposed the amendment.
[20] Jerry Taylor, Esq. of Farris Mathew Branan Bobango & Hellen made the following suggestion:

> The definition of "outpatient diagnostics center" in subsection (19) should be modified so that it specifically applies only to diagnostic imaging centers that are not limited to use by or under the supervision of, a specified physician or physician group. A suggested definition is:

"Outpatient Diagnostic Center" means any institution, facility or place that primarily performs diagnostic imaging procedures on an outpatient basis only, and is available for use by, or under the supervision of, physicians other than the specified physician, his or her group practice, or employees thereof. 'Primarily' as used herein means at least 50% of the gross revenues or 50% of the patient encounters are directly related to diagnostic imaging."

[21] Mr. John Wellborn of Development Support Group submitted the following comment:

The Agency may wish to consider something like this definition:

"ODC means any agency, institution, facility or place which performs outpatient diagnostic procedures (a) with mobile or fixed equipment listed in B.I.C. (e.g., MRI, PET, gamma knife, etc.), or (b) with other mobile or fixed equipment with an aggregate fair market value exceeding $1,500,000, excluding maintenance contracts and any equipment which is used exclusively to serve private physician practices."

This would give the Agency review of proposed diagnostic providers who intend to compete with existing ODC's, hospitals, and physicians in serving the public. It would leave private practices alone in their decisions about how best to serve their own patients, unless they are attempting to acquire the very expensive modalities listed in B.I.C., such as MRI, etc. It would let equipment vendors continue to set up minor diagnostic equipment rooms to serve specific medical practices under service contracts with the practices.

[22] T. Scott Noonan, Esq. of Bass, Berry & Sims submitted the following comment re. the definition of "outpatient diagnostic center." [paraphrased from a letter to Reid A. Brogden, Esq., General Counsel for the Agency]

Current Guidance: I understand from our conversation that currently there is no bright line rule or any real guidance in this area. I also understand based on our conversation that a physician practice should be able to provide some diagnostic tests to outside patients without the need for an ODC CON. In evaluating such a situation, it is my understanding that HSDA would look at all of the facts and circumstances, including the physician practice's volume or percentage of diagnostic tests performed on outside patients and whether the physician practice actively advertises or markets such activity. You indicated that it would be difficult for HSDA or the Tennessee Attorney General to bring an enforcement action due to the lack of clear guidance in this area. If such an enforcement action were brought, the physician practice would have thirty (30) days to cease all activity subject to the enforcement action and come into compliance with HSDA's interpretation on this issue.

Medicare IDTF "Substantial Portion" Test: As we discussed in our conversation, presumably a physician practice that provides diagnostic tests to outside patients, but that is not required to enroll in Medicare as an independent diagnostic testing facility (or IDTF), would not be required to obtain an ODC CON. As requested, I have enclosed some information regarding Medicare's "substantial portion" (or 30%) test as to when a physician practice must enroll in Medicare as an IDTF. Based on informal guidance from the Centers for Medicare & Medicaid Services ("CMS"), we believe that a non-radiologist physician or a non-radiologist physician group practice does not have to enroll as an IDTF if he or it provides less than a "substantial portion" (or 30%) of the diagnostic tests to Medicare patients who are not their patients (i.e., outside patients). Patients are considered by CMS to be patients of the physician/group practice if (a) they have a prior relationship with the physician or group practice **or** (b) the physician or group practice is also billing for office visit examinations and/or evaluation and management codes with respect to the patient. If the physician/group practice exceeds the 30% limit, he or it may need to enroll as a Medicare IDTF. CMS utilizes different criteria when providing guidance for radiologists/radiology group practices (please see the enclosed materials).

Tennessee Outpatient Diagnostic Center Definition: As you know, Tennessee regulations currently define an ODC as "any agency, institution, facility or place which primarily performs diagnostic procedures on an outpatient basis only." Since Tennessee uses a "primarily" standard, as opposed to CMS's "substantial portion" standard, we believe it would be fair to say that a 50% test is the current Tennessee standard since primarily as generally defined means chiefly, principally or for the most part (i.e., more than 50%).

[23] Agency Staff proposed the amendment because "Person" is defined in the new statute.
[24] Agency Staff proposed the amendment because "Rehabilitation" is defined in the new statute.
[25] Commissioner Flowers suggested that "[d]ue to the use of zip codes and portion of counties in service areas, which helps more clearly define the population used to calculate need, I would suggest that we add the language ", portion of county," between "county" and "or counties".
[26] Agency Staff proposed the amendment because Sub units are no longer distinguished as such by the Department of Health.
[27] Commissioner Flowers suggested the language.